# CHAPTER 3

# GETTING STARTED: PLANNING FOR THE HUMAN HEALTH EVALUATION IN THE RI/FS

This chapter discusses issues related to planning the human health evaluation conducted during the RI/FS. It presents the goals of the RI/FS process as a whole and the human health evaluation in particular (Sections 3.1 and 3.2). It next discusses the way in which a site that is divided into operable units should be treated in the human health evaluation (Section 3.3). RI/FS scoping is discussed in Section 3.4, and Section 3.5 addresses the level of effort and detail necessary for a human health evaluation.

## 3.1 GOAL OF THE RI/FS

The goal of the RI/FS is to gather information sufficient to support an informed risk management decision regarding which remedy appears to be most appropriate for a given site. The RI/FS provides the context for all site characterization activity, including the human health evaluation. To attain this goal efficiently, EPA must identify and characterize hazards in a way that will contribute directly to the selection of an appropriate remedy. Program experience has shown that Superfund sites are complex, and are characterized by heterogeneous wastes, extreme variability in contamination levels, and a variety of environmental settings and potential exposure pathways. Consequently, complete characterization of a site during the RI/FS, in the sense of eliminating uncertainty, is not feasible, cost-effective, or necessary for selection of appropriate remedies. This view has motivated the "streamlined approach" EPA is taking to help accomplish the goal of completing an RI/FS in 18 months at a cost of $750,000 per operable unit and $1.1 million per site. The streamlined approach recognizes that the elimination of all uncertainties is not possible or necessary and instead strives only for sufficient data to generally characterize a site and support remedy selection. The resulting remedies are flexible and incorporate specific contingencies to respond to new information discovered during remedial action and follow-up.

## 3.2 GOAL OF THE RI/FS HUMAN HEALTH EVALUATION

As part of the effort to streamline the process and reduce the cost and time required to conduct the RI/FS, the Superfund human health evaluation needs to focus on providing information necessary to justify action at a site and to select the best remedy for the site. This should include characterizing the contaminants, the potential exposures, and the potentially exposed population sufficiently to determine what risks need to be reduced or eliminated and what exposures need to be prevented. It is important to recognize that information should be developed only to help EPA determine what actions are necessary to reduce risks, and not to fully characterize site risks or eliminate all uncertainty from the analysis.

In a logical extension of this view, EPA has made a policy decision to use, wherever appropriate, standardized assumptions, equations, and values in the human health evaluation to achieve the goal of streamlined assessment. This approach has the added benefit of making human health evaluation easier to review, easier to understand, and more consistent from site to site. Developing unique exposure assumptions or non-standard methods of

risk assessment should not be necessary for most sites. Where justified by site-specific data or by changes in knowledge over time, however, non-standard methods and assumptions may be used.

## 3.3 OPERABLE UNITS

Current practice in designing remedies for Superfund sites often divides sites into operable units that address discrete aspects of the site (e.g., source control, ground-water remediation) or different geographic portions of the site. The NCP defines operable unit as "a discrete action that comprises an incremental step toward comprehensively addressing site problems." RI/FSs may be conducted for the entire site and operable units broken out during or after the feasibility study, or operable units may be treated individually from the start, with focused RI/FSs conducted for each operable unit. The best way to address the risks of the operable unit will depend on the needs of the site.

The human health evaluation should focus on the subject of the RI/FS, whether that is an operable unit or the site as a whole. The baseline risk assessment and other risk information gathered will provide the justification for taking the action for the operable unit. At the same time, personnel involved in conducting the human health evaluation for a focused RI/FS must be mindful of other potential exposure pathways, and other actions that are being contemplated for the site to address other potential exposures. Risk analysts should foresee that exposure pathways outside the scope of the focused RI/FS may ultimately be combined with exposure pathways that are directly addressed by the focused RI/FS. Considering risks from all related operable units should prevent the unexpected discovery of high multiple pathway risks during the human health evaluation for the last operable unit. Consider, for example, a site that will be addressed in two operable units: a surface soil cleanup at the contamination source and a separate ground-water cleanup. Risks associated with residuals from the soil cleanup and the ground-water cleanup may need to be considered as a cumulative total if there is the potential for exposure to both media at the same time.

## 3.4 RI/FS SCOPING

Planning the human health evaluation prior to beginning the detailed analysis is an essential step in the process. The RPM must make up-front decisions about, for example, the scope of the baseline risk assessment, the appropriate level of detail and documentation, trade-offs between depth and breadth in the analysis, and the staff and monetary resources to commit.

Scoping is the initial planning phase of the RI/FS process, and many of the planning steps begun here are continued and refined in later phases. Scoping activities typically begin with the collection of existing site data, including data from previous investigations such as the preliminary assessment and site inspection. On the basis of this information, site management planning is undertaken to identify probable boundaries of the study area, to identify likely remedial action objectives and whether interim actions may be necessary or appropriate, and to establish whether the site may best be remedied as one site or as several separate operable units. Once an overall management strategy is agreed upon, the RI/FS for a specific project or the site as a whole is planned.

The development of remedial alternatives usually begins during or soon after scoping, when likely response scenarios may first be identified. The development of alternatives requires:

- identifying remedial action objectives;
- identifying potential treatment, resource recovery, and containment technologies that will satisfy these objectives; and
- screening the technologies based on their effectiveness, implementability, and cost.

Remedial alternatives may be developed to address a contaminated medium, a specific area of the site, or the entire site. Alternative remedial actions for specific media and site areas either can be carried through the FS process separately or combined into comprehensive alternatives for the entire site. The approach is flexible to allow alternatives to be considered in combination at various points in the process. The RI/FS guidance discusses planning in greater detail.

## 3.5 LEVEL OF EFFORT/LEVEL OF DETAIL OF THE HUMAN HEALTH EVALUATION

An important part of scoping is determining the appropriate level of effort/level of detail necessary for the human health evaluation. Human health evaluation can be thought of as spanning a continuum of complexity, detail, and level of effort, just as sites vary in conditions and complexity. Some of the site-specific factors affecting level of effort that the RPM must consider include the following:

- number and identity of chemicals present;
- availability of ARARs and/or applicable toxicity data;
- number and complexity of exposure pathways (including complexity of release sources and transport media), and the need for environmental fate and transport modeling to supplement monitoring data;
- necessity for precision of the results, which in turn depends on site conditions such as the extent of contaminant migration, characteristics of potentially exposed populations, and enforcement considerations (additional quantification may be warranted for some enforcement sites); and
- quality and quantity of available monitoring data.[1]

This manual is written to address the most complex sites, and as a result not all of the steps and procedures of the Superfund human health evaluation process described in this manual apply to all remedial sites. For example, Section 6.6 provides procedures and equations for estimating chemical intakes through numerous exposure routes, although for many sites, much of this information will not apply (e.g., the exposure route does not exist or is determined to be relatively unimportant). This manual establishes a generic framework that is broadly applicable across sites, and it provides specific procedures that cover a range of sites or situations that may or may not be appropriate for any individual site. As a consequence of attempting to cover the wide variety of Superfund site conditions, some of the process components, steps, and techniques described in the manual do not apply to some sites. In addition, most of the components can vary greatly in level of detail. Obviously, determining which elements of the process are necessary, which are desirable, and which are extraneous is a key decision for each site. All components should not be forced into the assessment of a site, and the evaluation should be limited to the complexity and level of detail necessary to adequately assess risks for the purposes described in Sections 3.1 and 3.2.

Planning related to the collection and analysis of chemical data is perhaps the most important planning step. Early coordination among the risk assessors, the remainder of the RI/FS team, representatives of other agencies involved in the risk assessment or related studies (e.g., ATSDR, natural resource trustees such as the Department of the Interior, state agencies), and the RPM is essential and preferably should occur during the scoping stage of the RI/FS. Detailed guidance on planning related to collection and analysis of chemical data is given in Chapter 4 of this manual.

# ENDNOTE FOR CHAPTER 3

1. All site monitoring data must be subjected to appropriate quality assurance/quality control programs. Lack of acceptable data may limit by necessity the amount of data available for the human health evaluation, and therefore may limit the scope of the evaluation. Acceptability is determined by whether data meet the appropriate data quality objectives (see Section 4.1.2).